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# Pesticide Assessment Guidelines, Subdivision L Hazard Evaluation: Nontarget Insects Series 141-1, 141-2, and 141-5. Honey Bee Studies. Addendum 1 on Data Reporting

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# PESTICIDE ASSESSMENT GUIDELINES

## SUBDIVISION L

## HAZARD EVALUATION:

## NONTARGET INSECTS

Series 141-1, 141-2 and 141-5

Honey Bee Studies

ADDENDUM 1 ON DATA REPORTING

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ADDENDUM 1 to Pesticide Assessment Guidelines, Subdivision L, Hazard Evaluation: Nontarget Insects (EPA-540/9-82-019 and NTIS Order Number PB83-153957), October, 1982

**16. Abstract (Limit: 200 words)**

The Data Reporting Guideline (DRG) for the Honey Bee Studies, Series 141-1, 141-2 and 141-5, gives guidance to pesticide registrants on the format for their study report so that the Agency can review it efficiently. It clarifies sections in the existing Pesticides Assessment Guidelines, Subdivision L, on data reporting and provides an outline for study reports and describes the topics and the order in which they should be addressed. Examples of tables are also provided. This guideline actually contains formats for the preparation of reports for three studies: Honey Bee Acute Contact $LD_{50}$, Series 141-1; Honey Bee-Toxicity of Residues on Foliage, Series 141-2; and Field Testing for Pollinators, Series 141-5. Data submitters can use the DRG in preparing their reports for submission to EPA to meet 40 CFR 158 requirements for the registration of pesticides.

The DRG for Series 141-1, 141-2, and 141-5, Honey Bee Studies is the only DRG published by the National Technical Information Service as an addendum to Subdivision L of the Pesticide Assessment Guidelines.

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Subdivision L - Honey Bee Studies

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PESTICIDE ASSESSMENT GUIDELINES

NONTARGET INSECTS

Honey Bee Studies

Subdivision L, Series 141-1, 141-2 and 141-5

DATA REPORTING

INTRODUCTION

A. Purpose

To provide a data reporting format for the following studies: Honey Bee Acute Contact $LD_{50}$, Honey Bee - Toxicity of Residues on Foliage, and Field Testing for Pollinators.

B. Objective

These Data Reporting Guidelines are designed to aid the petitioner/ registrant in generating reports which are compatible with the Agency's review process. Data submitters are encouraged to submit complete reports following these guidances for efficient review by the Agency. These guidances pertain to the substance of the data report. PR Notice 86-5, effective on November 1, 1986 (available from the Registration Support and Emergency Response Branch, Office of Pesticide Programs, US EPA), pertains to the physical formating of reports (which are referred to as "studies") and submittal packages. Some of the requirements in PR Notice 86-5 are mandatory.

RESPONSE TO PUBLIC COMMENTS

There were no comments concerning these specific guidelines in response to the request for public comments announced in the the FEDERAL REGISTER notice of October 15, 1986 (51 FR 36753).

PESTICIDE ASSESSMENT GUIDELINES

NONTARGET INSECTS

Honey Bee Acute Contact $LD_{50}$

Subdivision L, Series 141-1

DATA REPORTING

GUIDELINE

The following describes the order and format for a study report item by item.

TITLE/COVER PAGE

Refer to PR Notice 86-5.

TABLE OF CONTENTS

The Table of Contents should indicate the overall organization of the study, including table and figures. It must follow the title, data confidentiality, and GLP (if appropriate) pages as described in PR Notice 86-5.

I. SUMMARY/INTRODUCTION

A. Sponsor: (Name of study owner);

B. Name(s) of principal investigator(s);

C. Location of study;

D. Location of raw data and final report;

E. Material: (Common/Trade name);

F. Subject: (Final or Draft report) Acute Contact $LD_{50}$;

G. Test Doses: (Control, #, #, #, #, # micrograms/bee);

H. Test Dates: Initiation (Date treated) and Termination (Date - last day of observation);

I. Length of Study;

J. Results: ($LD_{50}$ value, 95% confidence limits);

K. Test Material: (Chemical name, formulation, percent active ingredient);

L. Source of test bees; and

M. Species and strain of test bees.

II. MATERIALS/METHODS

This section is a narrative which would include the following items.

A. Test Substance

1. Identification (these items may be submitted by the laboratory or the sponsor):

   a. Chemical name;
   b. Composition (qualitative and quantitative description);
   c. Molecular structure;
   d. Percent active ingredient; and
   e. Source, lot number or code.

2. Preparation of test material (control/treatment):

   a. Vehicle used to dissolve or dilute the test substance;
   b. Preparation methods; and
   c. Any adjuvants used.

B. Test Insects

1. Source of supply of test bees;
2. Methods used to obtain test bees from colonies; and
3. Age of test bees.

C. Dosage

1. Amount of test material per bee;
2. Method of administration; and
3. Rationale for selection of method, route, or frequency, if different from that recommended in Subdivision L.

D. Methods

1. Number of treatment levels;
2. Number of bees per treatment level;
3. Method of assigning bees to treatment and control groups;
4. Method used to determine treatment levels;
5. Size of cages;
6. Number of bees per cage;
7. Number of controls;
8. Type of controls;
9. Environmental conditions (ambient temperature, humidity, etc.);
10. Source and availability of food and water;
11. Length of total observation period;
12. Frequency and duration of each observation; and
13. Criteria for determining effects.

E. Statistical Analysis

1. Cite references; and
2. Provide rationale for deviations from the cited method.

III. DISCUSSION/RESULTS

A. $LD_{50}$ in micrograms per bee, with 95% confidence limits; no-observed-effect level; slope of the dose response line, if the method provides a slope. (Optional graphs, printouts, and other calculations may be attached to the report).

B. Detailed description of the nature, incidence, time of occurrence, severity, and duration of all observed toxic effects, including death and any other abnormal or unusual signs.

C. Indicate the test procedures which deviate from the EPA guidelines and provide a rationale for the change.

IV. CONCLUSIONS

This is a summation of the DISCUSSION/RESULTS section, above.

V. TABLES/FIGURES

VI. REFERENCES

VII. APPENDICES

This is optional. You may attach graphs, raw data, printouts, etc., which may further support the study.

Examples of acceptable data tables

| Treatment and Rate | Number of bees treated | Replicate | Number dead 24 hrs. 48 hrs. | |
|---|---|---|---|---|
| | | A | | |
| | | B | | |
| | | C | | |
| | | | | |

| Treatment and Rate | Number Dead 24 HOURS | | 48 HOURS | | |
|---|---|---|---|---|---|
| | Rep. A | Rep. B | Rep. A | Rep. B | |
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| Control | | | | | |
| | | | | | |

PESTICIDE ASSESSMENT GUIDELINES

NONTARGET INSECTS

Honey Bee - Toxicity of Residues on Foliage

Subdivision L, Series 141-2

DATA REPORTING

GUIDELINE

The following describes the order and format for a study report item by item.

TITLE/COVER PAGE

Refer to PR Notice 86-5.

TABLE OF CONTENTS

The Table of Contents should indicate the overall organization of the study, including tables and figures. It must follow the title, data confidentiality, and GLP (if appropriate) pages as described in PR Notice 86-5.

I. SUMMARY/INTRODUCTION

A. Sponsor: (Name of study owner);

B. Name(s) of principal investigator(s);

C. Location of study;

D. Location of raw data and final report;

E. Material: (Common/Trade name);

F. Subject: (Final or Draft report) Residual Toxicity to Honey Bees;

G. Test Doses: (Control, #, #, #, #, # pounds active ingredient per acre);

H. Test Dates: Initiation (Date of application), and Termination (Date of last day of observation);

I. Length of Study;

J. Results: (Mortality at #, #, # hours post-treatment for each application rate);

K. Test Material: (Chemical name, formulation, percent active ingredient);

L. Source of test bees;

M. Type of crop treated; and

N. Species and strain of test bees.

II. MATERIALS/METHODS

This section is a narrative which would include the following items.

A. Test Substance

1. Identification (these items may be submitted by the laboratory or the sponsor):

   a. Chemical name;
   b. Composition (qualitative and quantitative description);
   c. Molecular structure;
   d. Percent active ingredient; and
   e. Source, lot number or code.

2. Preparation of test material:

   a. Carrier used to dilute the test pesticide;
   b. Any adjuvants used; and
   c. Preparation methods.

B. Test Insects

1. Source of supply of test bees;
2. Methods used to obtain test bees from colonies; and
3. Age of test bees.

C. Treatment

1. Amount of test material in pounds active ingredient per acre;
2. Method of application;
3. Name of crop treated; and
4. Rationale for selection of method, route, or frequency, if different from that recommended in Subdivision L.

D. Methods

1. Number of treatment levels (application rates);
2. Number of bees exposed per treatment level and time interval;
3. Method of assigning bees to treatment and control groups and method of assigning field plots;
4. Method used to determine treatment levels;
5. Method used to harvest treated foliage;
6. Size of cages;
7. Amount of treated foliage per cage;
8. Number of bees per cage;

9. Number of controls;
10. Environmental conditions;

    a. Weather conditions during and after application; and
    b. Temperature and humidity data for the period following application;

11. Source and availability of food and water;
12. Length of total observation period;
13. Frequency and duration of each observation; and
14. Criteria for determining effects.

E. Statistical Analysis

1. Cite references; and
2. Provide rationale for deviations from the cited method.

III. DISCUSSION/RESULTS

A. Percent mortality of test bees at each treatment level and time interval.

B. Detailed description of the nature, incidence, time of occurrence, severity, and duration of all observed toxic effects, including death and any other abnormal or unusual signs.

C. Indicate the test procedures which deviate from the EPA guidelines and provide a rationale for the change.

IV. CONCLUSIONS

This is a summation of the DISCUSSION/RESULTS section, above.

V. TABLES/FIGURES

VI. REFERENCES

VII. APPENDICES

This is optional. You may attach graphs, raw data, printouts, etc., which may further support the study.

Example of acceptable data table

Effect of Insecticide Treatments on Alfalfa to Honey Bees
(24-hour % mortality of bees caged on foliage samples)

| Treatment | Rate | Age of Residues | | | |
|---|---|---|---|---|---|
| | | x hr. | x hr. | x days | x days |
| | | | | | |

PESTICIDE ASSESSMENT GUIDELINES

NONTARGET INSECTS

Field Testing for Pollinators

Subdivision L, Series 141-5

DATA REPORTING

GUIDELINE

The following describes the order aand format for a study report item by item.

TITLE/COVER PAGE

Refer to PR Notice 86-5

TABLE OF CONTENTS

The Table of Contents should indicate the overall organization of the study, including tables and figures. It must follow the title, data confidentiality, and GLP (if appropriate) pages as described in PR Notice 86-5.

I. SUMMARY/INTRODUCTION

A. Sponsor: (Name of study owner);

B. Name(s) of principal investigator(s);

C. Location of study;

D. Location of raw data and final report;

E. Material: (Common/Trade name);

F. Subject: (Final or Draft report) Field Testing for Pollinators;

G. Test Doses;

H. Test Dates: Initiation (Date treated) and Termination (Date - last day of observation);

I. Length of Study;

J. Results;

K. Test Material: (Chemical name, formulation, percent active ingredient);

L. Source of test bees; and

M. Species and strain of test bees.

II. MATERIALS/METHODS

This section is a narrative which would include the following items.

A. Test Substance

1. Identification (these items may be submitted by the laboratory or the sponsor):

   a. Chemical name;
   b. Composition (qualitative and quantitative description);
   c. Molecular structure;
   d. Percent active ingredient; and
   e. Source, lot number or code.

2. Preparation of test material (control/treatment):

   a. Vehicle used to dissolve or dilute the test substance;
   b. Preparation methods; and
   c. Any adjuvants used.

B. Test Insects

Source of supply of test bees.

C. Treatment

1. Amount of test material (per acre, per colony, etc.);
2. Method of administration; and
3. Rationale for selection of method, route, or frequency.

D. Methods

1. Number of treatment levels;
2. Number of bees per treatment level;
3. Method of assigning bees to treatment and control groups and method of assigning field plots;
4. Method used to determine treatment levels;
5. Size of cages or colonies, if appropriate;
6. Number of bees per cage or colony;
7. Number of controls;
8. Type of controls;
9. Environmental conditions (ambient temperature, humidity, weather conditions, etc. during and after application);
10. Source and availability of food and water;
11. Length of total observation period;
12. Frequency and duration of each observation; and
13. Criteria for determining effects.

E. Statistical Analysis

1. Cite references; and
2. Provide rationale for deviations from the cited method.

III. DISCUSSION/RESULTS

A. Observed adverse effects on bees/bee colonies due to treatments. (Optional graphs, printouts, and other calculations may be attached to the report).

B. Detailed description of the nature, incidence, time of occurrence, severity, and duration of all observed toxic effects, including death and any other abnormal or unusual signs.

C. Indicate the test procedures which deviate from those agreed upon during pre-test consultation with the Agency. Provide a rationale for the changes.

IV. CONCLUSIONS

This is a summation of the DISCUSSION/RESULTS section, above.

V. TABLES/FIGURES

VI. REFERENCES

VII. APPENDICES

This is optional. You may attach graphs, raw data, printouts, etc., which may further support the study.